K101123

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510(k) Summary (per 21 CFR 807.92)

Name of Submitter:	BMEYE B.V. Academic Medical Center, Suite K2-245 Meibergdreef 9. 1105 AZ Amsterdam, The Netherlands
Contact Person:	Mr J Grijpma BMEYE BV T: +31 20 5665838, F: +31 20 6976424, E: john.grijpma@bmeye.com
Date Prepared:	February 26, 2009
Trade Names:	Nexfin Model 2, Trade name CC Nexfin
Classification	Class II
Classification Name	CFR 870.1130, System, measurement, blood pressure, non-invasive, DXN CFR 870.2770, Plethysmograph, impedance, DSB CFR 870.2700, Oximeter, DQA
Predicate:	The Nexfin Model 2 is substantially equivalent to the Nexfin Model 1 (K072049) and the Masimo Radical 7 (K080238)
Device description	The BMEYE CC Nexfin hemodynamic monitor is a non-invasive monitor that enables the continuous assessment of a patient's hemodynamic function based on the scientific method of Peňáz - Wesseling. The device measures continuous non-invasive blood pressure (Systolic, Diastolic and Mean) and heart rate as well as a Cardiac Output (CO), which is derived, non-invasively, from the blood pressure waveform. The monitor also calculates derived hemodynamic parameters. The operation of the blood pressure and cardiac output measurement is identical to the operation in Nexfin Model 1 (K072049). The CC Nexfin enables in addition the simultaneous measurement of SpO2 and SpHb using a pulse-CO oximetry sensor. The Nexfin Model 2 is to be used in combination with Masimo oximetry sensors. (K090238)
Intended Use:	The BMEYE CC Nexfin is intended to, non-invasively and continuously, measure blood pressure, hemodynamic parameters, functional saturation of arterial hemoglobin (SpO2), and total hemoglobin concentration (SpHb) in adult patients. The CC Nexfin monitor should be calibrated with a thermodilution measurement, or other accurate reference estimation of cardiac output, to ensure optimal accuracy of cardiac output. The CC Nexfin monitor does not feature (physiological) alarms. The device is intended for use by physicians or other properly trained medical personnel in a hospital or other appropriate clinical setting
Technology	The device employs identical technology for blood pressure and cardiac output measurement as was implemented in the predicate device (Nexfin Model 1), and uses the Masimo Rainbow SET technology for the measurement of SpHb and SpO2.
Functional/ Safety Testing:	The CC Nexfin has successfully undergone safety testing as well as functional testing to demonstrate equivalence to its predicate devices. The following quality

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assurance measures were applied to the device:

- Risk Analysis
- Requirements Review
- Design reviews
- Code Inspections
- Verification and Validation
- Bench Testing (for Cardiac Output functionality in Nexfin Model 1)
- Clinical Testing (for NBP functionality, in Nexfin Model 1)
- H/W and S/W Implementation Verification Testing of the SpO2 and SpHb functions by Masimo
- Biocompatibility Testing
- Safety Testing

Conclusion: The results of this testing demonstrates that the device is safe and effective and substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

BMEYE B.V.
c/o Mr. William Greenrose
Official Correspondent &
Regulatory Consultant for BMEYE B.V.
Qserve America, Inc.
220 River Road
Claremont, NH 03743-5647

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Re: K101123
Trade/Device Name: CC Nexfin
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive blood pressure measurement system
Regulatory Class: Class II (two)
Product Code: DXN DSB DQA
Dated: April 16, 2010
Received: April 22, 2010

Dear Mr. Greenrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101123

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Device Name: Nexfin Model 2 (trade name CC Nexfin)

Indications For Use:

The BMEYE CC Nexfin is intended to, non-invasively and continuously, measure blood pressure, hemodynamic parameters, functional saturation of arterial hemoglobin (SpO2), and total hemoglobin concentration (SpHb) in adult patients. The pulse-oximetry component of CC Nexfin is indicated for use during both no motion and motion conditions and for patients who are well or poorly perfused. The CC Nexfin monitor does not feature (physiological) alarms, therefore the continuous availability of pulse-oximetry data should be treated as a series of spot-checks rather than continuous monitoring. The CC Nexfin monitor should be calibrated with a thermodilution measurement, or other accurate reference estimation of cardiac output, to ensure optimal accuracy of cardiac output. The device is intended for use by physicians or other properly trained medical personnel in a hospital or other appropriate clinical setting.

Prescription Use __✓_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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